



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: (510) 337-6732

October 1, 1997

**WARNING LETTER**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: 2939691

Mr. Robert Walter  
President  
Accucare Medical Corp.  
2900 Telegraph Ave.  
Oakland, California 94609

Dear Mr. Walter:

During a September 5 and 9, 1997, inspection of your home respiratory care company located at 2900 Telegraph Ave., Oakland, California 94609, FDA Investigator Carl Anderson documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's repacking of Oxygen, USP. These deviations cause the drug to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to adequately test Oxygen USP for purity [21 CFR 211.165(a)]. Your firm may comply with this regulation by obtaining an acceptable certificate of analysis (COA) from your supplier; however, the COA which you presently receive is not acceptable, in that the test method is not listed, and you have not established the reliability of the supplier's analyses through validation of the supplier's test results at appropriate intervals as required by 21 CFR 211.84(d)(2).
2. Failure to establish written procedures for receiving and confirming the identity of liquid oxygen as required by 21 CFR 211.80(a) and 21 CFR 211.84(d)(2).

Your Oxygen USP is misbranded within the meaning of Section 503 (b)(4) of the FD & C Act, in that its label fails to bear the statement, "Caution: Federal law prohibits dispensing without prescription." [21 CFR 201.100(b)(1)]

Mr. Robert Walter  
Oakland, California  
October 1, 1997

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The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

Enclosed are a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of a speech by Mr. Duane Sylvia of FDA's Office of Compliance, Division of Manufacturing and Product Quality, Center for Drug Evaluation and Research; and 21 CFR Part 211. The Compressed Medical Gases Guideline and Mr. Sylvia's speech contain useful information on how to comply with the requirements of 21 CFR Part 211.

Federal agencies are advised of the issuance of all warning letter about drugs so that they may take this information into account when considering the award of contracts.

Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products (Section 304) and for injunction (Section 302) of the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time needed to complete the corrections.

Please submit your response to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070, attention: Philip R. Lindeman, Compliance Officer.

Sincerely,

*Charles D. Moss* Acting District Director

*For*

Patricia C. Ziobro  
District Director

Enclosures:

21 CFR Part 211

Speech by Mr. Duane Sylvia

Compressed Medical Gases Guideline

Mr. Robert Walter  
Oakland, California  
October 1, 1997

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cc:

Ms. Marcia Walter  
Vice President & Office Manager  
Accucare Medical Corp.  
2900 Telegraph Ave.  
Oakland, California 94609